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(54) Method and apparatus for bilateral intra-aortic bypass.

(57) A bilateral intra-aortic bypass graft (150) and method and apparatus for repairing an abdominal aortic aneurysm (151) includes two tubular grafts (160A,160B) which are intraluminally delivered to the aorta (152) and secured to the aorta (152) by the expansion and deformation of two expandable and deformable tubular members (166A,166B).

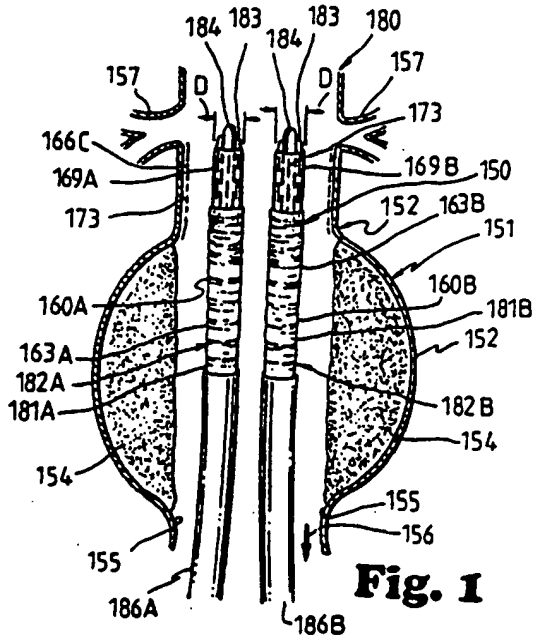

Fig. 1

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ed with the graft by expanding and inflating a portion of the catheter which contacts the tubular member. Because of the relatively large diameter of the catheter and associated graft necessary for implantation within the aorta, some difficulties have been sometimes encountered, such as spasms associated with the access body vessel such as the femoral artery. Additional problems sometimes encountered with this method or repairing an abdominal aortic aneurysm have been kinking and/or twisting of the flexible, collapsible graft during and/or after implantation of the graft.

Accordingly, prior to the development of the present invention, there has been no bilateral intra-aortic bypass graft for intraluminal delivery, or method and apparatus for repairing an abdominal aortic aneurysm, which: does not have a relatively high morbidity and mortality rate; does not have an extended recovery period; does not require suturing the graft to the remaining aorta wall; permits the existing thrombosis therein to support and reinforce the graft; is suitable for older patients with chronic illnesses; is less susceptible to kinking and/or twisting of the graft; and is able to use a smaller diameter delivery system. Therefore, the art has sought a bilateral intra-aortic bypass graft for intraluminal delivery, and method and apparatus for repairing an abdominal aortic aneurysm which is believed to: not have a high morbidity and mortality rate; does not require an abdominal incision and general anesthesia; not require an extended recovery period; not require suturing the graft to the remaining aortic wall; permit the existing aortic wall and thrombosis therein to be retained to reinforce and support the aortic graft; be suitable for patients having other chronic illnesses; be less susceptible to kinking and/or twisting of the graft and permit the use of a smaller diameter delivery system.

SUMMARY OF THE INVENTION

In accordance with the invention, the foregoing advantages have been achieved through the method and apparatus for bilateral intra-aortic graft of the present invention. The method for repairing an abdominal aortic aneurysm in an aorta having two iliac arteries associated therewith may include the steps of: connecting a first tube to a first expandable and deformable, tubular member; connecting a second tube to a second expandable and deformable, tubular member; disposing the first tube and first tubular member upon a first catheter, disposing the second tube and second tubular member upon a second catheter, each catheter having an expandable, inflatable portion with the tubular members disposed upon the expandable, inflatable portions; intraluminally delivering the first and second tubes, tubular members, and catheters to the aorta and disposing at least a portion of each tube within the abdominal aortic aneurysm; and expanding the expandable, inflatable portion of each catheter to expand and deform the tubular members to force the tubular members radially outwardly into contact with the aorta and each other, to secure the tubular members and a least a portion of each tube within the aorta, whereby the tubes provide a bilateral fluid passageway through the abdominal aortic aneurysm.

Another feature of the present invention may include the step of simultaneously expanding the expandable, inflatable portions of each catheter. An additional feature of the present invention is that the first and second tubes may each have first and second ends, the first end of each tube being connected to a tubular member and being disposed within the aorta; and the second end of the first tube may be disposed within one of the iliac arteries, and the second end of the second end may be disposed within the other iliac artery.

A further feature of the present invention is that a third expandable and deformable, tubular member may be connected to the second end of the first tube; a fourth expandable and deformable, tubular member may be connected to the second end of the second tube; and the third and fourth tubular members are expanded and deformed to force the third and fourth tubular members radially outwardly into contact with an iliac artery by the expansion of the expandable, inflatable portion of each catheter associated with each tube. Another feature of the present invention may include the steps of forming each tube of a plurality of expandable and deformable, tubular members, each tubular member having a longitudinal axis, by aligning the plurality of tubular members with their longitudinal axes being substantially parallel with other, each tubular member being detached, and spaced apart, from adjacent tubular members; and embedding the plurality of tubular members within a layer of deformable and expandable plastic material. The plastic material may be silicone, polytetrafluoroethylene, expanded polytetrafluoroethylene, or expanded polyurethane.

An additional feature of the present invention may include the step of simultaneously expanding the expandable, inflatable portion of each catheter to simultaneously expand and deform the first and second tubular members and the plurality of tubular members of each tube which are embedded in the deformable and expandable plastic material. A further feature of the present invention may include the step of connecting the first and second tubular members to the first and second tubes by embedding a portion of the second ends of the first and second tubular members in the deformable and expandable plastic material of the tube to which it is to be connected.

A further feature of the present invention may include the steps of: disposing a fifth expandable and deformable tubular member upon a third catheter

to be connected.

In accordance with the present invention, the foregoing advantages have also been achieved through the present apparatus for repairing an abdominal aortic aneurysm in an aorta having two iliac arteries associated therewith. The present invention includes: first and second tubes, each tube having first and second ends and a wall surface disposed between the two ends; first and second expandable and deformable tubular members, each expandable and deformable tubular members having first and second ends and a smooth outer wall surface disposed between the first and second ends, the first end of a tube being secured to a second end of a tubular member, the expansion and deformation of the tubular members being controllable; and two catheters, each catheter having an expandable, inflatable portion associated therewith, the tubular members being releasably mounted upon the inflatable portion of each catheter, whereby upon inflation of the expandable, inflatable portion of each catheter, the tubular members are forced radially and outwardly into contact with the aorta and each other to remain secured thereto, whereby the tubes, secured to the tubular members, provide a bilateral passageway through the abdominal aortic aneurysm.

A further feature of the present invention is that each tube may be formed of a plurality of expandable and deformable, tubular members, each tubular member having a longitudinal axis, the plurality of tubular members being aligned with their longitudinal axes being substantially parallel with each other, each tubular member being detached, and spaced apart, from adjacent tubular members; and the plurality of tubular members may be embedded within a layer of a deformable and expandable plastic material. An additional feature of the present invention is that the expandable, inflatable portion of each catheter may extend along a portion of the length of each catheter a distance greater than the combined length of each tube and tubular member, whereby upon expansion and inflation of each expandable, inflatable portion of each catheter, each tubular member and its connected tube are simultaneously expanded.

The bilateral intra-aortic bypass graft for intraluminal delivery, and method and apparatus for repairing an abdominal aortic aneurysm of the present invention, when compared to previously proposed prior art grafts and methods and apparatus for repairing aneurysms, are believed to have the advantages of: a lower mortality rate; shortened recovery periods; not requiring suturing a graft to the aorta; utilizing the existing aortic wall and thrombosis therein to support and reinforce the aortic graft; being suitable for use with patients having other chronic illnesses; being less susceptible to kinking and/or twisting of the graft and permitting the use of a small diameter delivery system.

BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings:

FIG. 1 is a partial cross-sectional view of an abdominal aortic aneurysm in the process of being repaired in accordance with the present invention;

FIG. 2 is partial cross-sectional view of an aorta, abdominal aortic aneurysm, and iliac aneurysm, in the process of being repaired in accordance with the present invention;

FIG. 3 is a partial cross-sectional view of a portion of the aorta of FIG. 1, illustrating a tubular member in the process of being expanded within the aorta;

FIG. 4 is a partial cross-sectional view of the aorta of FIG. 3, illustrating a tubular member being fully expanded;

FIG. 5 is a partial cross-sectional view of the abdominal aortic aneurysm of FIG. 2, illustrating the expansion of the bilateral intra-aortic bypass graft of the present invention;

FIG. 6 is a cross-sectional view taken along line 6-6 of FIG. 5;

FIG. 7 is a cross-sectional view taken along line 7-7 of FIG. 5; and

FIG. 8 is a cross-sectional view taken along line 8-8 of FIG. 5

FIG. 9 is a perspective view of a portion of a tube which forms a part of the bilateral intra-aortic bypass graft of the present invention;

FIG. 10A is a partial, perspective view of a portion of the bilateral intra-aortic bypass graft of the present invention;

FIG. 10B is a partial, perspective view of a portion of the bilateral intra-aortic bypass graft of the present invention;

FIG. 11 is a partial cross-sectional view of the aorta and abdominal aortic aneurysm of FIG. 2, illustrating the bilateral intra-aortic bypass graft of the present invention in place in the aorta and abdominal aneurysm;

FIG. 12 is a cross-sectional view taken along line 12-12 of FIG. 11;

FIG. 13 is a cross-sectional view taken along line 13-13 of FIG. 11;

FIG. 14 is a cross-sectional view taken along line 14-14 of FIG. 11;

FIG. 15 is a partial cross-sectional view of another embodiment of a bilateral intra-aortic bypass graft of the present invention;

While the invention will be described in connection with the preferred embodiment, it will be understood that it is not intended to limit the invention to that embodiment. On the contrary, it is intended to cover all alternatives, modifications, and equivalents, as may be included within the spirit and scope of the invention as defined by the appended claims.

expanded polytetrafluoroethylene, and expanded polyurethane. It is preferred that all of the foregoing materials be porous to allow for an intimal layer to form on the tubes 160. Additionally, tubes 160A, 160B can be made by the replamineform replicated life forms process, which is a method for fabricating uniformly microporous materials from marine skeletal structures. The foregoing described fabric materials can be knitted or woven, and can be warp or weft knitted. If the material is warp knitted, it may be provided with a velour, or towel like surface, which speeds up clotting of blood which contacts tubes 160A, 160B in order to increase the attachment, or integration, of tubes 160A, 160B to aorta 152, or to assist the integration of tubes 160A, 160B to the thrombosis 154. Tubes 160A, 160B can also be made of a bio-erodible , or degradable material, such as albumin or collagen or a collagen coated material. A tube 160 which is bio-erodible, would erode and dissolve, or degrade, over a period of time; however, it is believed that a layer of endothelium, or skin, will grow as the tubes 160A, 160B erode, the new layers of endothelium, or skin, provide a new, fluid impervious lining within aneurysm 151. In some procedures, it might be desirable to make tubes 160A, 160B of a fluid impervious material. Additionally, tubes 160A, 160B, as well securing means 165, or tubular members 166A, 166B, could have a coating of a biologically inert material, such as TEFLON® or porous polyurethane.

If any of the foregoing described materials are used for the manufacture of tubes 160A, 160B, the first ends 161A, 161B of tubes 160A, 160B may be connected to the second ends 168A, 168B of the tubular members 166A, 166B, as by a plurality of conventional sutures of polypropylene, DACRON®, or any other suitable material. Preferably, the ends 161A, 161B of tubes 160A, 160B overlap and cover the second ends 168A, 168B of tubular members 166A, 166B, such overlapping being approximately 50% of the length of tubular 166A, 166B. The first ends 161A, 161B of tubes 160A, 160B, which overlap the second ends 168A, 168B of tubular members 166A, 166B, are preferably constructed so that they are radially expandable, whereby the first ends 161A, 161B of tubes 160A, 160B can conform with the second, expanded and deformed diameter D' of the second ends 168A, 168B of the tubular members 166A, 166B. If tubes 160A, 160B are woven, the weave of the materials at its first ends 161A, 161B is looser, so that the desired radial expansion can be obtained. The intermediate portions 171A, 171B (FIG. 11) of tubes 160A, 160B disposed between first and second ends 161A, 161B, 162A, 162B thereof, are preferably not substantially radially expandable when tubes 160A, 160B are manufactured from the foregoing described fabric, or fabric like, materials.

With reference to FIGS. 9, 10A and 10B, another embodiment of tubes 160 of bypass graft 150 are illustrated. Each tube 160A, 160B is preferably formed of a plurality of expandable and deformable, tubular members 201. Each tubular member 201 has a longitudinal axis, with a plurality of tubular members 201 being aligned with their longitudinal axes being substantially parallel with each other, as illustrated by center line 202. Each tubular member 201 is detached, and spaced apart, from adjacent tubular members 201. Tubular members 201 are of the same construction of tubular members 166 previously described, however, the length of tubular members 201 and number of slots 173 extending along the length of each tubular member 201 may be varied depending upon the total length of tube 160. After the plurality of tubular members 201 have been aligned as illustrated in FIG. 9, with tubular members 201 being disposed with their first unexpanded diameter D which permits intraluminal delivery of the tubular members 201, the plurality of tubular members 201 are disposed in a suitable, conventional jig, die, or mold. The plurality of tubular members 201 are then embedded within a layer 202 of a deformable and expandable plastic material, such embedding being carried out through use of any conventional molding process. The plastic material may be silicone, polytetrafluoroethylene, expanded polytetrafluoroethylene, expanded polyurethane, or any other plastic material have the requisite strength characteristics to be utilized as a bypass graft, as well as have the requisite compatibility with the human body in order to be used as a graft, or implant material, without being rejected by the patient's body, as well as have the ability to expand as tubular members 201 are expanded, as will be hereinafter described, and be able to maintain the expanded configuration when tubular members 201 have a second, expanded and deformed diameter D' as illustrated in FIG. 10A.

The resulting tube 160, after the plurality of tubular members 201 have been embedded within the layer 202 of plastic material, is a tube 160 having a substantially smooth inner and outer surface 203, 204 formed by the layer 202 of plastic material in which tubular members 201 are embedded. It is believed that such tubes 160 will be substantially non-collapsible and not subject to kinking and/or twisting upon being implanted.

Tube 160 of FIG. 10A may be connected to the second end 168 of tubular member 166 in the manner previously described, such as by a plurality of conventional sutures; however, preferably the first and second tubular members 166A, 166B are connected to the first and second tubes 160A, 160B by embedding a portion of the second ends 168A, 168B of the first and second tubular members 160A, 160B in the plastic material 202 of the tube 160 to which tubular members 166A, 166B are to be connected, as illustrated in FIG. 10B. As seen in FIG. 10B, the upper end 167, or leading edge, of tubular member 166 is

tion of tubular members 166A, 166B is controlled by the expansion of balloons 183 of catheters 181A, 181B in a conventional manner. When apparatus 180 is being intraluminally delivered, catheters 181A, 181B, tubular members 166A, 166B, and tubes 160A, 160B are preferably enclosed by conventional catheter sheathes 186A, 186B which are removed, as shown in FIG. 1, as apparatus 180 is disposed in its desired location within aorta 152.

If tubular members 166A, 166B, are utilized in connection with a fabric type tube 160, as previously described, balloon 183 of catheter 181 may have a length which extends from slightly beyond the first end 167 of tubular member 166, and to a position slightly beyond the second end 168 of tubular member 166. As illustrated in FIG. 5, if apparatus 180 includes tubes 160 constructed in a manner as described in FIGS. 9, 10A, and 10B, inflatable portion 182, or balloon 183 associated with each catheter 181 extends along a portion of the length of each catheter a distance greater than the combined length tube 160 and its associated tubular member 166, as illustrated in FIG. 5. Thus, upon expansion and inflation of each expandable and inflatable portion 182, or balloon 183, associated with each catheter 181, each tubular member 166A, 166B, is simultaneously expanded along with its connected tube 160A, 160B, including the plurality of tubular members 201 embedded within the layer 202 of plastic material of tubes 160A, 160B (FIGS. 9, 10A, 10B). Deflation of balloons 183 permits the withdrawal of catheters 181 and release of balloons 183 and catheters 181 from bypass graft 150 after graft 150 has been disposed in the configuration illustrated in FIG. 5. When tubes 160 are utilized of the construction illustrated in FIGS. 9, 10A, 10B, as shown in FIG. 5, the resulting bilateral passageway 191 formed in aorta 152 and aneurysm 151 is believed to be substantially non-collapsible , because of the presence of the plurality of tubular members 201 embedded within tubes 160A, 160B.

When implanting a bypass graft 150 of the construction illustrated in FIG. 15, first, second, third, and fourth tubular members 166A, 166B, 166A', 166B' may be simultaneously expanded and deformed into the expanded configuration illustrated in FIG. 15, as by use of the catheters 182 illustrated in FIG. 5, along with tubes 160A, 160B.

As illustrated in FIGS. 1, 2, 5, and 6, tubular members 166A, 166B, are initially disposed within aorta 152 substantially even and on the same level as each other, at which time sheathes 186 are removed and balloons 183A, 183B are simultaneously expanded as illustrated in FIGS. 5 and 6, until tubular members 166A, 166B are in an abutting relationship with each other and against aorta 150. Upon final inflation and expansion of the balloons 183A, 183B to force tubular members 166A, 166B into their final configuration illustrated in FIGS. 11 and 12, the abutting portions 210A, 210B of tubular members 166A, 166B, are flattened against each other into the configuration shown in FIG. 12, whereby the initially present gaps 211 (FIG. 6) between adjacent tubular members 166A, 166B, are closed off and removed.

FIGS. 13 and 14 illustrate bypass graft 150 after it has been implanted for a period of time, whereby the aneurysm 151 has thrombosed about tubes 160A, 160B and into contact therewith, and bilateral passageways 191A, 191B are thus disposed within aneurysm 151.

With reference to FIGS. 3 and 4, an alternative method for repairing an abdominal aortic aneurysm in an aorta 152 is illustrated. In this embodiment, bilateral intra-aortic bypass graft 150 includes a fifth expandable and deformable tubular member 166C of the same construction of the first through fourth tubular members 166A, 166B, 166A', 166B' as previously described. Prior to the intraluminal delivery of tubular members 166A, 166B, and tubes 160A, 160B as previously described in connection with FIGS. 1, 2, and 5, the fifth tubular member 166C is intraluminally delivered by a third catheter 181' and expanded from its first diameter D" to its second, expanded and deformed diameter D"', as illustrated in FIG. 4, to secure the fifth tubular member 166C within the aorta 152. After the fifth expandable tubular member 166C has been implanted within aorta 152, as shown in dotted lines in FIG. 1, the remaining elements of bypass graft 150 are implanted within aorta 152 and aneurysm 151 as previously described in connection with FIGS. 1, 2, and 5. Upon expansion of first and second tubular members 166A, 166B, as previously described, those tubular members 166A, 166B, will be in abutting relationship with each other, as illustrated in FIG. 12, and will also be secured within aorta 152, via their expansion and deformation, into contact with fifth tubular member 166C which is secured in aorta 152.

It is believed that the use of fifth tubular member 166C will provide adequate anchorage for the tubular members 166A, 166B of bypass graft 150, and equalize forces exerted upon aorta 152 by the expansion of tubular members 166A, 166B. Fifth tubular member 166C has a final expanded diameter D"' which is approximately twice the size of the expanded diameter D' of tubular members 166A, 166B. Because fifth tubular member 166C does not have a tube 160 attached thereto, its delivery system, or catheter 181' and sheath 186' can be smaller, and they can be intraluminally delivered without any of the previously described disadvantage as sociated with prior art aortic grafts, having a large diameter tube connected thereto.

It is to be understood that the invention is not limited to the exact details of construction, operation, exact materials or embodiments shown and described, as obvious modifications and equivalents will be apparent to one skilled in the art. For example, the ex-

ethane.

13. The bilateral intra-aortic bypass graft of claim 8, wherein the first and second tubular members are connected to the first and second tubes by embedding a portion of the second ends of the first and second tubular members in the deformable and expandable plastic material of the tube to which it is to be connected.

14. The bilateral intra-aortic bypass graft of claim 1, including a fifth expandable and deformable tubular member, wherein:
(a) after the fifth expandable and deformable, tubular member has been intraluminally delivered and expanded and deformed to force the fifth tubular member radially outwardly into contact with the aorta to secure the fifth tubular member within the aorta; and
(b) after the expansion and deformation of the first and second tubular members, the first and second tubular members are disposed within the fifth expandable tubular member in an abutting relationship with each other and with the fifth expandable tubular member, whereby the first and second tubular members may be secured within the aorta and within the fifth tubular member.

15. The bilateral intra-aortic bypass graft of claim 14, wherein each tube is formed of a plurality of expandable and deformable tubular members, each tubular member having a longitudinal axis with the plurality of tubular members being aligned with their longitudinal axes being substantially parallel with each other; each tubular member being spaced apart from adjacent tubular members with a single, flexible connector member being disposed between adjacent tubular members; and the plurality of tubular members are embedded within a layer of a deformable and expandable plastic material.

16. The bilateral intra-aortic bypass graft of claim 15, wherein the plastic material is silicone.

17. The bilateral intra-aortic bypass graft of claim 15, wherein the plastic material is polytetrafluoroethylene.

18. The bilateral intra-aortic bypass graft of claim 17, wherein the plastic material is expanded polytetrafluoroethylene.

19. The bilateral intra-aortic bypass graft of claim 15, wherein the plastic material is expanded polyurethane.

20. The bilateral intra-aortic bypass graft of claim 15, wherein the first and second tubular members are connected to the first and second tubes by embedding a portion of the second ends of the first and second tubular members in the deformable and expandable plastic material of the tube to which it is to be connected.

21. An apparatus for repairing an abdominal aortic aneurysm in an aorta having two iliac arteries associated therewith, comprising:
(a) first and second tubes, each tube having first and second ends and a wall surface disposed between the two ends;
(b) first and second expandable and deformable tubular members, each expandable and deformable tubular member, having first and second ends and a smooth outer wall surface disposed between the first and second ends, the first end of a tube being secured to a second end of a tubular member, the expansion and deformation of the tubular members being controllable; and
(c) two catheters, each catheter having an expandable, inflatable portion associated therewith, the tubular embers being releasably mounted upon the inflatable portions of each catheter, whereby upon inflation of the expandable, inflatable portion of each catheter, the tubular members are forced radially outwardly into contact with the aorta and each other to remain secured thereto, whereby the tubes, secured to the tubular members, provide a bilateral passageway through the abdominal aortic aneurysm.

22. The apparatus of claim 21, wherein each tube is formed of a plurality of expandable and deformable, tubular members, each tubular member having a longitudinal axis, the plurality of tubular members being aligned with their longitudinal axes being substantially parallel with each other, each tubular member being detached, and spaced apart, from adjacent tubular members; and the plurality of tubular members are embedded within a layer of a deformable and expandable plastic material.

23. The apparatus of claim 22, wherein the expandable, inflatable portion of each catheter extends along a portion of the length of each catheter for a distance greater than the combined length of each tube and tubular member, whereby upon expansion and inflation of each expandable, inflatable portion of each catheter, each tubular member and its connected tube are simultaneously expanded.

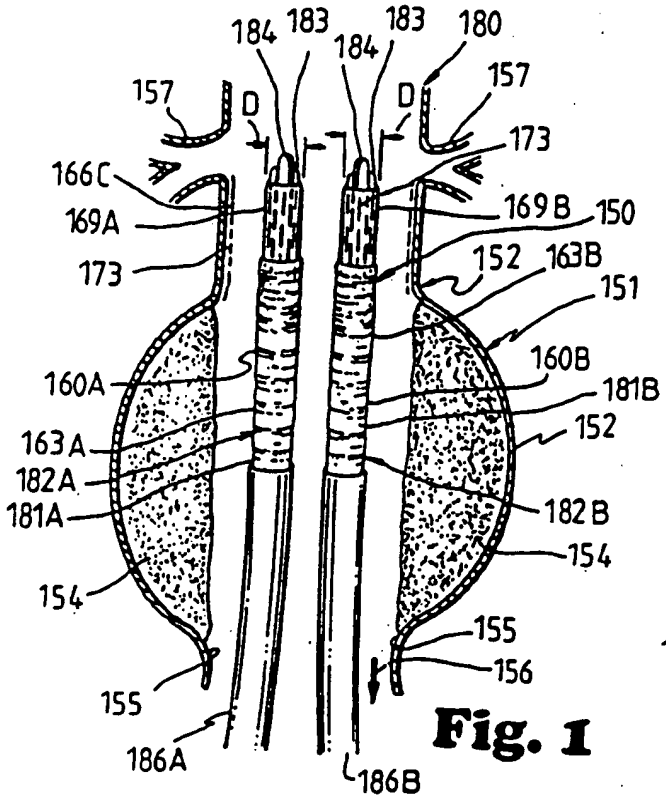

Fig. 1

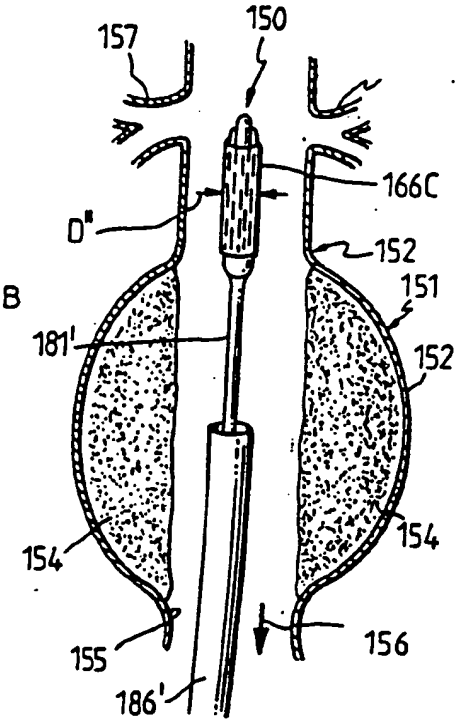

Fig. 3

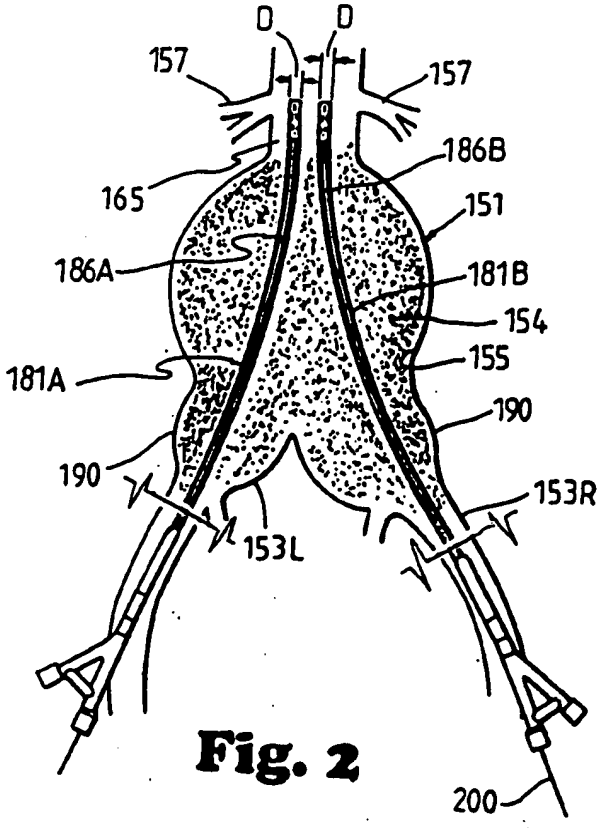

Fig. 2

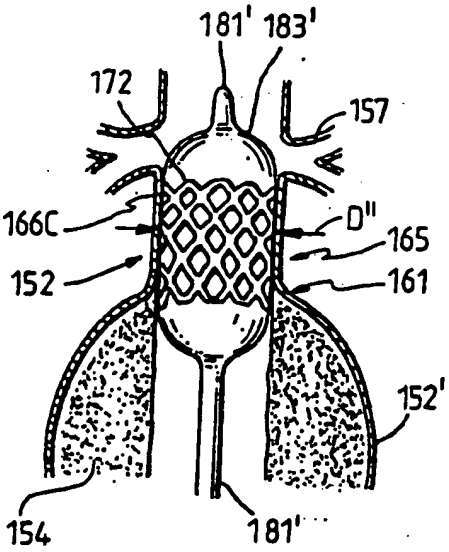

Fig. 4

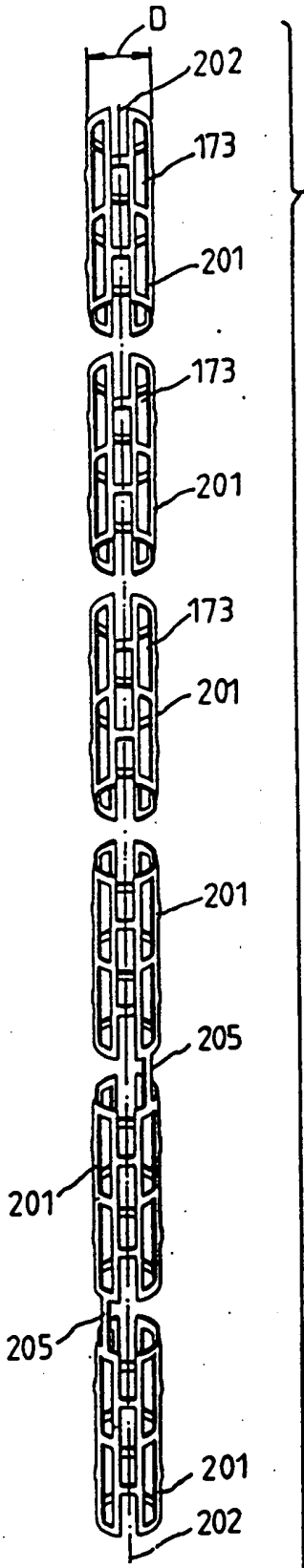

Fig. 9

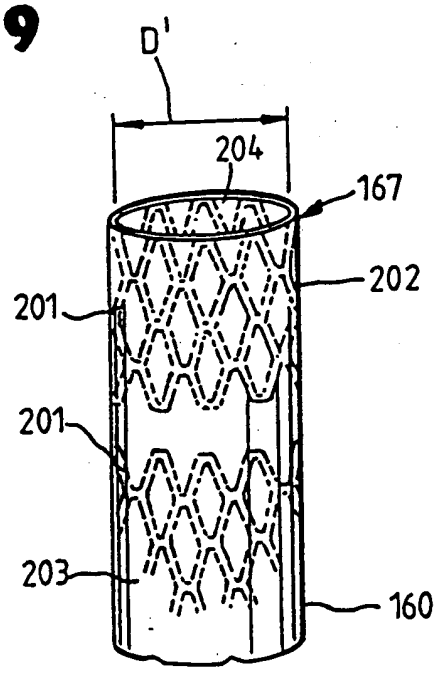

Fig. 10A

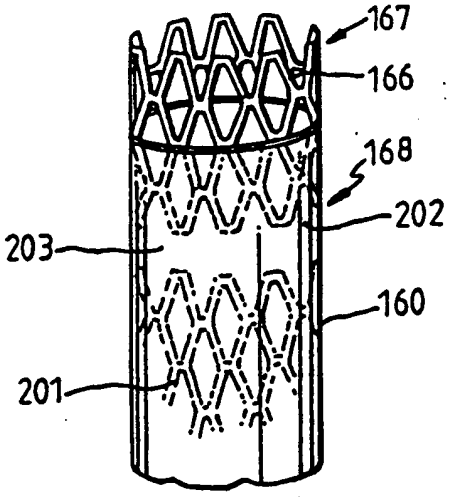

Fig. 10B

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 93 30 0047

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
Y	EP-A-0 461 791 (BARONE ET AL.) * column 8, line 12 - column 9, line 2 * * claims 1-9; figures *	1,3-32	A61F2/06
Y	EP-A-0 364 787 (EXPANDABLE GRAFTS PARTNERSHIP) * column 12, line 23 - column 14, line 9; figures *	1,3-32	
A	US-A-3 657 744 (ERSEK) * claim 1; figure 1 *	1	
A	US-A-4 562 596 (KORNBERG)	-	
P,A	EP-A-0 479 557 (BARONE ET AL.) * abstract * * figure 1 *	1	

TECHNICAL FIELDS SEARCHED (Int. Cl.5)

A61F
A61M

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	23 FEBRUARY 1993	GODOT T.

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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